

BASIS FOR THE AMENDMENTS

It has now been made clear in the claims that only the faces of an intermediate polyolefin sheet are surface crosslinked, consistent with the disclosure.

REMARKS

Entry of this amendment and favorable reconsideration of this application is requested.

Claims 10, 13, 15, 16, 18 and 19 are in the case.

Preliminary, it is to be noted that the finality of the rejection is premature. More particularly, the embodiment to which the claims were amended in the last amendment of October 24, 2002, i.e., to restrict them to embodiment b), did not present a new issue inasmuch as amended Claim 10 was limited to an embodiment so also specifically claimed, as note Claim 12. The embodiment as defined by amended Claim 10 thus is not a new issue, but was so specifically claimed at the time the Examiner finally rejected the claims.

Accordingly, withdrawal of the finality of the Official Action of December 23, 2002 is requested.

Claims 10, 13 and 15 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Hitchcock, of record.

Claims 10, 15, 18 and 19 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Noda et al, newly cited.

Claims 10 and 15 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Atchison et al, newly cited.

Claims 10, 13 and 15 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Hosoda et al in view of Hitchcock.

Claim 13 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over Noda et al or Atchison et al in view of Hitchcock.

Claim 16 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over Hitchcock, Noda et al, Atchison et al or Hosoda et al, each in view of Hurley et al.

Claims 18 and 19, also stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Hitchcock or Atchison et al in view of Noda et al.

Claims 18 and 19 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Hosoda et al and Hitchcock further in view of Noda et al.

These rejections are traversed. The invention relates to a process for preparing a sheet of a crosslinked polyolefin foam expanded in an essentially unidirectional expansion only in its thickness, comprising surface-crosslinking only one or both faces of an intermediate polyolefin sheet to be expanded, these faces being perpendicular to the direction of expansion, and expanding and crosslinking the so formed sheet only in its thickness.

The claimed process obviates problems associated with prior art procedures and results in a foamed product of superior properties, as so shown by the examples in the case. Specifically, by blocking lateral expansion of the foam during its expansion, unidirectional expansion only in its thickness is permitted. This is accomplished by the claimed process which embodiment manifestly is not obvious.

More particularly, Hitchcock relates to the preparation of a foamed thermoplastic resin sheet by conveying a radiation crosslinked, plastic resin sheet in a horizontally supported state while applying uniform tension to the edge of the width of the foamed sheet. In other words, while freely permitting expansion in the thickness of the sheet, expansion is also effected in the length and width directions, i.e., the foamed sheet having a substantially

uniform orientation across the sheet. No unidirectional expansion only in the thickness of the sheet thus is present in the sheet of Hitchcock.

The Examiner agrees that Hitchcock teaches expansion at least in two directions (thickness and width). How then can it be reasonably urged that Hitchcock anticipates the claimed invention? Clearly, such is not a valid conclusion, the Examiner's assertion being contraindicated by the examples in this reference. Specifically, as is evident from Example 1 of Hitchcock, the width of the sheet fed into the horizontal hot air expansion apparatus was 30 inches. After expansion, however, its width had increased to approximately six feet, i.e., 72 inches, a more than twice increase in width. Note column 5, lines 39 and 59-60. The same is true in Example 2, as note column 6, line 36. Manifestly, thus, expansion is not unidirectional only in the thickness, but also in width. While substantial uniform orientation is effected by Hitchcock across the web, such uniform orientation also involves expansion in width, contrary to the express requirement of the claims.

It is well-established that in order to urge anticipation, within the meaning of 35 U.S.C. § 102, the prior art must necessarily and inevitably produce the claimed results. Note *ex parte Levy* 17 USPQ2d 1461. Such clearly is not the case here where the conditions in the reference are such to realize expansion in at least two directions, not unidirectional expansion. The Examiner's assumption that unidirectional expansion is realized by Hitchcock is contrary to its express teaching, as discussed above. Applicants, on the other hand, are expanding and crosslinking the formed sheet only in its thickness, as so specifically called for by the claims, such being contrary to the process of Hitchcock in which expansion in the width direction is also effected due to the tension across the face of the sheet also maintained by Hitchcock.

Hurley et al is relied upon by the Examiner only for asserted obviousness of a subsidiary claimed feature. As such, it manifestly does not cure the basic deficiencies of Hitchcock to make obvious the claimed invention.

Accordingly, withdrawal of the rejections predicated on Hitchcock, also in view of Hurley et al is requested.

With regard to the rejections based on Noda et al and Atchison et al, newly cited, the following is submitted in traversal thereof.

In both of these references, crosslinking is effected throughout the foamable sheet, not only on one or both surfaces thereof. More particularly, in Noda et al while different energy ionizing radiation are applied to the surfaces and the body of the foamable resin sheet, nevertheless, the resin sheet manifestly will expand in all directions, no unidirectional expansion being involved.

Similarly, in Atchison et al the trivinyl isocyanurate enhancing the crosslinkability of an olefin polymer is present in admixture throughout the olefin polymer, expansion taking place with uniformity throughout the polymer being foamed. No unidirectional expansion manifestly also is involved in Atchison et al.

With regard to Hosoda et al, as far as it may be pertinent, it is directed to an embodiment no longer claimed. It is thus not apparent that the combined teachings of these references makes obvious the now-claimed invention when even Hitchcock, the reference combined with Hosoda et al, also does not make obvious the claimed invention, for reasons as pointed out and discussed above.

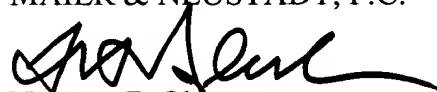
Hurley, additionally relied upon in these rejections, does not cure the basic deficiencies of the references, for the reason as pointed out above, this reference being relied upon only for asserted obviousness of a subsidiary claimed feature.

Withdrawal of the rejections of the claims under 35 U.S.C. § 102 and 103 thus is requested.

It is submitted that the claims define a patentable invention, their allowance is solicited.

Respectfully submitted,

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Marked-Up Copy

Serial No: 09/580,874

Amendment Filed: HEREWITH

IN THE CLAIMS

--10. (Twice Amended) A process for preparing a sheet of a crosslinked polyolefin foam expanded in an essentially unidirectional expansion only in its thickness, comprising surface-crosslinking only one or both faces of an intermediate polyolefin sheet to be expanded, these faces being perpendicular to the direction of expansion, and expanding and crosslinking the so formed sheet only in its thickness.--



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Ex parte Levy (BdPatApp&Int) 17 USPQ2d 1461

Ex parte Levy

U.S. Patent and Trademark Office, Board of Patent Appeals and Interferences 17 USPQ2d 1461

Decided October 16, 1990
No. 90-1864

Headnotes

PATENTS

1. Patentability/Validity - Anticipation - Identity of elements (§ 115.0704)

Factual determination of anticipation requires disclosure in single reference of every element of claimed invention, and examiner must identify wherein each and every facet of claimed invention is disclosed in applied reference.

2. Patentability/Validity - In general (§ 115.01)

Patentability/Validity - Anticipation - Prior art (§ 115.0703)

Initial burden of establishing prima facie basis to deny patentability rests upon examiner; examiner, if relying upon theory of inherency, must provide basis in fact and/or technical reasoning to reasonably support determination that allegedly inherent characteristic necessarily flows from teachings of applied prior art.

3. Patentability/Validity - Anticipation - Prior art (§ 115.0703)

Examiner erred by rejecting claims for biaxially oriented catheter balloon as anticipated by prior art which does not disclose such biaxially oriented balloon and which has not been shown to be inherently biaxially oriented.

4. Patentability/Validity - Obviousness - Relevant prior art - Particular inventions (§ 115.0903.03)

Examiner erred by rejecting claims for biaxially oriented balloon catheter under 35 USC 103 based upon combined disclosure of two prior art references, one of which was relied upon solely for disclosed use of high viscosity polyethylene terephthalate tubing and the other which was presupposed by examiner to disclose biaxially oriented catheter balloon, since examiner has not established that resulting catheter balloon using high viscosity tubing is biaxially oriented.

Case History and Disposition:

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Application of Stanley B. Levy, serial no. 287,234, filed Dec. 21, 1988, which is a division of serial no. 914,108, filed Oct. 1, 1986, now Re. 32,983, granted July 4, 1989; and a reissue of serial no. 510,812, filed July 5, 1983, now patent no. 4,490,421, granted Dec. 25, 1984, for balloon and manufacture thereof. From examiner's rejection of claims 13 through 17 and 25 (James Seidleck, primary

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examiner), applicant appeals. Reversed.

Attorneys:

Louis H. Rombach, Wilmington, Del., for appellant.

Judge:

Before Steiner, Tarring, and J. Smith, examiners-in-chief.

Opinion Text

Opinion By:

Steiner, examiner-in-chief.

This is an appeal from the final rejection of claims 13 through 17 and 25, which are all of the claims remaining in this application for reissue of U.S. Patent No. 4,490,421.

The subject matter on appeal is directed to a polymeric balloon exhibiting properties which enable its use as a catheter balloon for medical dilation procedures, such as coronary angioplasty wherein a catheter with a balloon at a distal end thereof is inserted into coronary arteries and inflated. The balloon must be capable of exerting sufficient pressure to dilate stenotic lesions without rupture of the balloon.

Claims 13 and 25, the only independent claims on appeal, read as follows:

13. *High molecular weight, biaxially oriented, flexible polymeric balloon having a wall tensile strength of at least 31,714 psi (218.86 MPa).*

25. *High molecular weight, biaxially oriented, flexible polyethylene terephthalate dilatation catheter balloon.*

The references relied upon by the examiner are:

Wyeth et al. (Wyeth)	3,733,309	May 15, 1973
Schjeldahl et al. (Schjeldahl '989)	4,413,989	Nov. 8, 1983 1
Schjeldahl et al. (Schjeldahl '000)	4,456,000	June 26, 1984 2

Claims 13, 14, 16, 17 and 25 stand rejected under 35 U.S.C. 102 as anticipated by Schjeldahl. Claims 13 through 17 stand rejected under 35 U.S.C. 103 based upon "Schjeldahl et al in view of Wyeth as set forth in the Final Rejection" (paragraph bridging pages 3 and 4 of the Answer). We reverse each rejection.

The Rejection of Claims 13, 14, 16, 17 and 25 Under 35 U.S.C. §102.

[1] The factual determination of anticipation requires the disclosure in a single reference of every element of the claimed invention. *In re Spada*, — F.2d —, 15 USPQ2d 1655 (Fed. Cir. 1990); *In re Bond*, — F.2d —, 15 USPQ2d 1566 (Fed. Cir. 1990); *Diversitech Corp. v. Century Steps, Inc.*, 850 F.2d 675, 7 USPQ2d 1315 (Fed. Cir. 1988); *Constant v. Advanced Micro-Devices, Inc.*, 848 F.2d 1560, 7 USPQ2d 1057 (Fed. Cir. 1988); *Alco Standard Corp. v. TVA*, 808 F.2d 1490, 1 USPQ2d 1337 (Fed. Cir. 1986); *In re Marshall*, 578 F.2d 301, 198 USPQ 344 (CCPA 1978); *In re Arkley*, 455 F.2d 586, 172 USPQ 524 (CCPA 1972). Moreover, it is incumbent upon the examiner to identify wherein each and every facet of the claimed invention is disclosed in the applied reference. *Lindemann Maschinenfabrik GmbH v. American Hoist and Derrick*, 730 F.2d 1452, 221 USPQ 481 (Fed. Cir. 1984).

Each of the independent claims on appeal defines a polymeric balloon which is "biaxially oriented." Ergo, in order to establish a *prima facie* basis to defeat the patentability of independent claims 13 and 25 under 35 U.S.C. §102, the examiner is obliged to point out

where Schjeldahl discloses a *biaxially oriented* polymeric balloon. The tenor of the final rejection and Answer presupposes that Schjeldahl discloses a biaxially oriented polymeric balloon. See, for example, page 5 of the Final Rejection wherein the examiner states

he reference clearly teaches a biaxially oriented balloon catheter, and states that it is made by injection blow molding.

See, also, page 5 of the Answer wherein the examiner states

rguments that the references don't disclose a biaxially oriented PET (polyethylene terephthalate) balloon catheter is contrary to what is *clearly stated* in the references (emphasis supplied).

The examiner does not point to, and we do not find, any express disclosure in Schjeldahl of a biaxially oriented polymeric balloon.

It would appear that the relevant evulgations in Schjeldahl which may have led the examiner to his determination are:

(a) an expander 3 formed *from* a thin, flexible inelastic, high tensile strength, *biaxially oriented* synthetic plastic material

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(column 2 of Schjeldahl '989, lines 63 through 65, emphasis supplied);

(b) The expander 30 is preferably formed *from* a suitable synthetic plastic material, such as *biaxially oriented* polypropylene, *by an injection blow molding operation* and, as such, is substantially inelastic in both the axial and radial directions and may, for example, have a finished wall thickness in the range of from 0.005 to 0.200 millimeters, 0.025 millimeters being typical (column 6 of Schjeldahl '989, lines 45 through 52, emphasis supplied);

(c) It has been found that an expander of the above-dimensional characteristics can withstand internal inflation pressure in excess of 7 atmospheres without fear of rupture (column 6 of Schjeldahl '989, lines 62 through 65);

(d) injection blow molding step used to form the expander 30 (column 8, lines 16 and 17);

(e) the expander 30 is formed *from* a *biaxially oriented* thin plastic material capable of withstanding relatively high internal pressures without rupture and without exceeding the elastic limit for the material itself (column 10 of Schjeldahl '989, lines 32 through 36, emphasis supplied);

(f) the expander 82 is preferably formed *from* a suitable synthetic plastic material such as *biaxially oriented polypropylene* or *biaxially oriented polyethylene terephthalate by an injection molding operation* and, as such, is substantially inelastic in both the axial and radial direction (column 12 of Schjeldahl '989, lines 22 through 37, emphasis supplied); and

(g) Apparatus as in claim 1 wherein said non-elastic expander member comprises a longitudinally extending thin, flexible, tubular element *formed from a biaxially oriented* synthetic plastic material surrounding said outer tubular member with opposed ends thereof

secured to said outer tubular member at spaced apart locations proximate said distal end thereof (claim 8 of Schjeldahl '989, emphasis supplied).

These excerpts do not justify the determination that Schjeldahl discloses a biaxially oriented polymeric balloon.

According to Schjeldahl, the *starting* material is a biaxially oriented synthetic plastic material, such as polyethylene terephthalate. The *final article*, i.e., the expander or catheter balloon, is *not characterized as biaxially oriented*. Moreover, it would appear to be *undisputed* that the *only* method disclosed by Schjeldahl for transforming the biaxially oriented *starting* plastic into the *final* catheter balloon, i.e., injection blow molding, is *not* capable of producing a biaxially oriented catheter balloon. In fact, it is *undisputed* that injection blow molding would *destroy* the biaxial orientation of the plastic starting material. We refer to the Belcher affidavits, Exhibits V, VI and VIII, 4 which factually set forth the differences between "injection blow molding" and "injection stretch blow molding," and support the conclusion that the "injection blow molding" process disclosed by Schjeldahl could not possibly produce a biaxially oriented polymeric balloon. 5

Indeed, the examiner agrees with appellant's position that injection blow molding could *not* produce a biaxially oriented balloon. See, for example, page 5 of the Final Rejection wherein the examiner states:

tatements that injection blow molding without stretching will not produce a biaxially oriented article are *true ...* (emphasis supplied).

The examiner goes on, in the same sentence, to state:

but since the reference produces a biaxially oriented article, clearly a stretching step must be used.

Again, on page 5 of the Answer, the examiner states:

Since Schjeldahl et al produces a biaxially oriented article it follows that a stretching step must be used in the injection blow molding process.

The inescapable facts are that Schjeldahl does not disclose a biaxially oriented catheter balloon and does not mention a stretching step.

[2] The examiner also relies upon the theory that Schjeldahl's catheter balloon is inherently biaxially oriented. On page 4 of the Answer, the examiner points out that inasmuch as the Patent and Trademark Office does not have the requisite laboratory equipment for testing, the burden shifts to appellant. However, the initial burden of establishing a *prima facie* basis to deny patentability to a claimed invention rests

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upon the examiner. *In re Piasecki*, 745 F.2d 1468, 223 USPQ 785 (Fed. Cir. 1984). In relying upon the theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic *necessarily* flows from the teachings of the applied prior art. *In re King*, 801

F.2d 1324, 231 USPQ 136 (Fed. Cir. 1986); *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540, 220 USPQ 303 (Fed. Cir. 1983); *In re Oelrich*, 666 F.2d 578, 212 USPQ 323 (CCPA 1981); *In re Wilding*, 535 F.2d 631, 190 USPQ 59 (CCPA 1976); *Hansgirg v. Kemmer*, 102 F.2d 212, 40 USPQ 665 (CCPA 1939). In our opinion, the examiner has not discharged that initial burden.

Schjeldahl does not provide any working example revealing the process conditions employed to produce the catheter balloon. We have *only* a general invitation to employ "injection blow molding." As previously discussed, it is undisputed that injection blow molding would *not* have produced a biaxially oriented balloon and would have destroyed the biaxially orientation of a polymeric starting material.

Schjeldahl does not disclose any particular tensile strength of the catheter balloon. We do not find sufficient factual basis or cogent scientific reasoning to support the conclusion that Schjeldahl's disclosure with respect to the ability of the catheter balloon to "withstand an internal inflation pressure in excess of 7 atmospheres without fear of rupture" (column 6 of Schjeldahl '989, lines 63 through 65) *necessarily* means that the catheter balloon is biaxially oriented. According to the membrane equation calculations reported in Levy's declaration (Exhibit IV), Schjeldahl's balloon could not possibly exhibit the tensile characteristics of a biaxially oriented balloon. Levy's calculations are *inconsistent* with those of Pinchuk (Exhibit III). Suffice it to say, the conflicting calculations taint the factual determination of inherency with impermissible conjecture. Indeed, the examiner, in the paragraph bridging pages 4 and 5 of the Answer, states that

the membrane equation used to determine the tensil [sic, tensile] strength can be manipulated to produce any desired value, and thus is misleading.

Nevertheless, the examiner goes on to favor Pinchuk's calculations by stating in that same paragraph that

certainly use of the typically used wall thickness disclosed in Schjeldahl et al with the average radius, as done in the Pinchuk Declaration would be reasonable.

As noted above, the conflicting results obtained by applying the membrane equation, and the examiner's acknowledgment that that equation "can be manipulated to produce any desired value," underscore the speculative nature upon which the determination of inherency rests.

We do not find sufficient cogent technical reasoning and/or objective evidence to support the conclusion that Schjeldahl's characterization of the catheter balloon as inelastic in the axial and radial direction *necessarily* means that the catheter balloon is biaxially oriented. The characteristic "inelastic," as employed by Schjeldahl, apparently means that the catheter balloon will expand to a preformed diameter to enable precise measurement of the pressures exerted on the inner wall of the artery during the dilation procedure (column 4 of Schjeldahl '989, lines 12 through 17).

[3] In summary, Schjeldahl does not disclose a biaxially oriented catheter balloon. We do not find a sufficient basis to support the determination that Schjeldahl's balloon is *inherently* (necessarily) biaxially oriented. *In re King, supra*; *W.L. Gore & Associates, Inc. v.*

Garlock, Inc., supra; In re Oelrich, supra; In re Wilding, supra; Hansgirk v. Kemmer, supra. Accordingly, the examiner's rejection of claims 13, 14, 16, 17 and 25, under 35 U.S.C. §102 as anticipated by Schjeldahl is reversed. 6

The Rejection of Claims 13 through 17 under 35 U.S.C. §103 Based upon the Combined Disclosures of Schjeldahl and Wyeth.

Wyeth is directed to producing high strength biaxially oriented polyethylene terephthalate beverage containers. The disclosed method involves stretching polyethylene terephthalate having a relatively high inherent viscosity; *e.g.*, at least about 0.85.

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It is apparent from the Final Rejection and Answer that the examiner's rejection of the appealed claims under 35 U.S.C. 103 is *not* predicated upon the theory that one having ordinary skill in the art would have been led to employ Wyeth's technique to produce a biaxially oriented balloon for use in Schjeldahl's catheter. Instead, the examiner presupposes that Schjeldahl discloses a biaxially oriented catheter balloon. The examiner relies upon Wyeth *solely* for the disclosed use of high viscosity polyethylene terephthalate tubing. We refer to page 6 of the Answer, first complete paragraph, wherein the examiner explains the rejection by stating:

Wyeth et al is not being combined with Schjeldahl et al, but merely shows the claimed high viscosity PET (polyethylene terephthalate) and supports the examiners [sic, examiner's] inherency arguments. 7 ... The examiner is not substituting the process of Wyeth et al into Schjeldahl et al since both disclose the same process. 8 Arguments that Wyeth et al can't be scaled down are irrelevant since the examiner is not seeking to scale down that reference to produce the claimed article.

[4] We have already concluded that the examiner factually erred in determining that Schjeldahl expressly or inherently discloses a biaxially oriented catheter balloon. Assuming, *arguendo*, the examiner correctly concluded that one having ordinary skill in the art would have been led to employ a high viscosity polyethylene terephthalate tubing in producing Schjeldahl's catheter balloon, the rejection under 35 U.S.C. §103 must fall because the examiner has not established that the resulting catheter balloon is biaxially oriented. *Uniroyal, Inc. v. Rudkin-Wiley Corp.*, 837 F.2d 1044, 5 USPQ2d 1434 (Fed. Cir. 1988).

Inasmuch as the examiner's rejection under 35 U.S.C. §103 is not predicated upon the theory that one having ordinary skill in the art would have been led to employ a conventional stretch blow molding technique, such as that disclosed by Wyeth, to produce Schjeldahl's catheter balloon, the motivation for such a combination is an issue which was not crystallized on appeal and was not confronted by appellant. However, in view of the examiner's gratuitous statement in the paragraph bridging pages 5 and 6 of the Answer, 9 we are constrained to address that issue.

There appears to be no dispute that one having ordinary skill in the art would have recognized the desirability of producing a biaxially oriented balloon for use in Schjeldahl's

catheter, since biaxially oriented materials were known to exhibit high tensile strengths. The thrust of the evidence relied upon by the examiner is that one having ordinary skill in the art would have simply resorted to a conventional stretch molding technique to produce a biaxially oriented balloon for use in Schjeldahl's catheter, specifically, *the technique employed by Wyeth to produce a beverage container*. See paragraph 4 of the Rydell affidavit executed April 25, 1988 and offered in support of the protest in parent application Serial No. 914,108, paragraph 5 of the Pinchuk affidavit (Exhibit III), and paragraphs 4 and 5 of the Kaufman affidavit (Exhibit XII). Interestingly enough, *Wyeth disagrees*. See page 5 of Wyeth's declaration (Exhibit XI). Wyeth points out various differences between the PET bottles produced by his disclosed process and the requirements of a catheter balloon, and then concludes that his process could *not* be used to produce a catheter balloon of the type disclosed by Levy.

We are persuaded by Belcher's affidavits and Wyeth's declaration, notwithstanding the affidavits of Rydell, Pinchuk and Kaufman, 10 that the known processes for producing

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biaxially oriented beverage containers, such as that disclosed by Wyeth, could not have been simply scaled down to produce a biaxially oriented catheter balloon for use in medical dilation procedures without the exercise of inventive skill. 11 Based upon the record before us, it would appear unrealistic to conclude that one having ordinary skill in the art would have been led to employ Wyeth's technique, which is designed to produce beverage containers, to produce Schjeldahl's catheter balloon, motivated by a *reasonable expectation* of obtaining a *biaxially oriented* polymeric catheter balloon. *In re O'Farrell*, 853 F.2d 894, 7 USPQ2d 1673 (Fed. Cir. 1988). The rejection under 35 U.S.C. §103 is also reversed.

REVERSED.

Footnotes

Footnote 1. Each of the Schjeldahl references contains essentially the same relevant disclosure. Accordingly, unless otherwise indicated, we have referred to these references collectively as "Schjeldahl," consistent with the approach adopted by both appellant and the examiner.

Footnote 2. See footnote 1.

Footnote 3. Schjeldahl characterizes the catheter balloon as an expander.

Footnote 4. Unless otherwise indicated, all exhibits mentioned are the exhibits to appellant's Brief.

Footnote 5. We recognize that a high burden of proof is required to demonstrate the inoperability of a United States patent. *In re Weber*, 405 F.2d 1403, 160 USPQ 549 (CCPA 1969); *In re Michalek*, 162 F.2d 229, 74 USPQ 107 (CCPA 1947). However, as noted above, Schjeldahl does not disclose a catheter balloon made of a biaxially oriented plastic. Therefore, appellant's evidence is not an attack on the operability of Schjeldahl, but quite relevant to the issue of inherency, *i.e.*, whether the catheter balloon disclosed by Schjeldahl is inherently biaxially oriented.

Footnote 6. There is evidence of record that Dupont, the assignee of the application, furnished biaxially oriented polyethylene terephthalate to Schjeldahl when he informed Dupont personnel that he required a thin, high strength polymeric film having a tensile strength in the range of 20,000-40,000 psi. See the Schjeldahl affidavit (Exhibit VIII) and the Dengler declaration executed on May 21, 1988 and appended to the protest submitted in parent application Serial No. 914,108. Such facts are not inconsistent with our determination that Schjeldahl does not disclose a biaxially oriented polyethylene terephthalate catheter balloon. The Rydell affidavit appended to the protest in the parent application does not persuade us that Schjeldahl expressly or inherently discloses a biaxially oriented polymeric catheter balloon. See Belcher's affidavit (Exhibit VI).

Footnote 7. Actually, according to the Final Rejection which is incorporated in the Answer,

it is the Examiner's position that it would be *prima facie* obvious to use the high viscosity polyethylene terephthalate of Wyeth in Schjeldahl et al to produce the claimed product (page 4, the only complete paragraph).

Footnote 8. It is apparent from our reversal of the examiner's rejection under 35 U.S.C. §102 that, in our opinion, Schjeldahl discloses neither a biaxially oriented catheter balloon nor a molding process which involves stretching.

Footnote 9. The noted statement provides:

Certainly in the least there was an *invitation* to make a biaxially oriented catheter balloon at the time of the Schjeldahl et al invention. Additionally injection stretch blow molding to produce biaxially oriented articles was well known at the time of the Schjeldahl et al invention (emphasis supplied).

Footnote 10. We agree with appellant that the credentials of Belcher and Wyeth in the relevant art appear more impressive than those of protestor's experts. According to the affidavit appearing as Appendix V, Belcher authored the chapter called "Blow Molding of Polymers" for the fifth edition of the Plastic Engineering Handbook of the Society of Plastics Industry. In addition, Belcher authored two chapters, one on "injection blow molding" and one on "stretch blow molding" for the Blow Molding Handbook of the Society of Plastics and Engineers. We consider Wyeth's opinion with respect to the capabilities of his own invention entitled to greater weight than the opinions of Rydell, Pinchuk and Kaufman.

Footnote 11. We find it somewhat unrealistic in light of the apparent disparities in size and function, Belcher's affidavits and Wyeth's declaration, that Pinchuk and Kaufman equate beverage bottles to catheter balloons. See paragraph 10 of the Pinchuk affidavit (Exhibit III),

wherein it is stated

s a blow molded polymeric article, a bottle and a catheter balloon are equivalent.

See, also, paragraph 4 of the Kaufman affidavit (Exhibit XII), wherein it is stated that

anyone with ordinary skill in the plastics art would know how to make a biaxially oriented PET balloon; it would be similar to making a biaxially oriented PET bottle because both catheter balloons and bottles are equivalent structures - they are both fluid containers.

- End of Case -



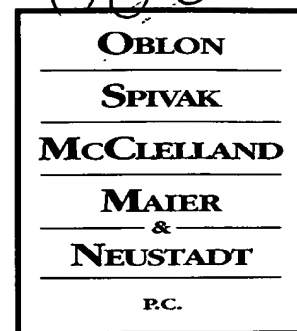
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Docket No.: 192592US0NPP CONT

ASSISTANT COMMISSIONER FOR PATENTS
WASHINGTON, D.C. 20231



ATTORNEYS AT LAW

RE: Application Serial No.: 09/580,874
Applicants: Michel M. LADANG, et al.
Filing Date: May 30, 2000
For: PROCESS FOR PREPARING A CROSSLINKED
POLYOLEFIN FOAM
Group Art Unit: 1733
Examiner: Goff

SIR:

Attached hereto for filing are the following papers:

Amendment Under 37 C.F.R. §1.116 + Marked-Up Copy; Ex parte Levy, 17 USPQ2d 1461

Our check in the amount of \$0.00 is attached covering any required fees. In the event any variance exists between the amount enclosed and the Patent Office charges for filing the above-noted documents, including any fees required under 37 C.F.R. 1.136 for any necessary Extension of Time to make the filing of the attached documents timely, please charge or credit the difference to our Deposit Account No. 15-0030. Further, if these papers are not considered timely filed, then a petition is hereby made under 37 C.F.R. 1.136 for the necessary extension of time. A duplicate copy of this sheet is enclosed.

Respectfully submitted,

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Docket No.: 192592US0NPP CONT

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WASHINGTON, D.C. 20231



ATTORNEYS AT LAW

RE: Application Serial No.: 09/580,874
Applicants: Michel M. LADANG, et al.
Filing Date: May 30, 2000
For: PROCESS FOR PREPARING A CROSSLINKED
POLYOLEFIN FOAM
Group Art Unit: 1733
Examiner: Goff

SIR:

Attached hereto for filing are the following papers:

Amendment Under 37 C.F.R. §1.116 + Marked-Up Copy; Ex parte Levy, 17 USPQ2d 1461

Our check in the amount of \$0.00 is attached covering any required fees. In the event any variance exists between the amount enclosed and the Patent Office charges for filing the above-noted documents, including any fees required under 37 C.F.R. 1.136 for any necessary Extension of Time to make the filing of the attached documents timely, please charge or credit the difference to our Deposit Account No. 15-0030. Further, if these papers are not considered timely filed, then a petition is hereby made under 37 C.F.R. 1.136 for the necessary extension of time. A duplicate copy of this sheet is enclosed.

Respectfully submitted,

OBLON, SPIVAK, McCLELLAND,
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